

7-13-05

Express Mail No. EK052556244US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Robert Michael Kalthoff et al.  
Application No.: 10/813,918  
Filed: March 31, 2004  
For: Secure Network Gateway for Accessible Patient Data and Transplant Donor Data

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IFW  
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TRANSMITTAL and CERTIFICATION OF SERVICE of  
THIRD PARTY SUBMISSION UNDER 37 C.F.R. § 1.99

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

RECEIVED  
JUL 18 2005  
GROUP 3600

Sir:

Enclosed herewith is a Third Party Submission Under 37 C.F.R. § 1.99 and the two prior art references cited therein. The Commissioner is authorized to charge the \$180 fee required by 37 C.F.R. § 1.99 and 1.17(p), and any other fees required in connection with this paper, to Deposit Account 16-2500.

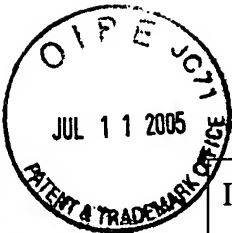
I HEREBY CERTIFY that I served copies of the enclosed Third Party Submission and prior art references on the applicants' attorney via first class mail pursuant to 37 C.F.R. §§ 1.248(a)(4) and 1.248(b) by mailing same to: Ryan Willis, Taft, Stettinius & Hollister LLP, 425 Walnut Street, Suite 1800, Cincinnati, OH 45202-3957. The date of service was July 8, 2005.

07/14/2005 AKELECH1 00000028 162500 10813918  
01 FC:1806 180.00 DA

Dated: July 11, 2005

Robert S. Mayer  
Reg. No. 38,544

Proskauer Rose LLP  
1585 Broadway  
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Sir:

Pursuant to 37 C.F.R. § 1.99 and MPEP 1134.01, the undersigned respectfully requests consideration of the following prior art publications in the above-identified application:

Item No.	Date of Publication	Title	Type of Publication
1	October 17, 2002	Paperless Organ Allocation Program (POAP)	PowerPoint presentation made to a group of Organ Procurement Organization directors on October 17, 2002, in Lake Buena Vista, FL
2	October 2002	Referrals, Reports, and Resources – OPO Management Suite – Developed by: Louisiana Organ Procurement Agency	Handout that was distributed at an October 2002 presentation to a group of Organ Procurement Organization directors in Lake Buena Vista, FL

A copy of each listed publication is enclosed herewith.

This submission is timely because the above-identified application published on May 12, 2004.

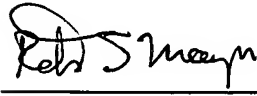
The Commissioner is authorized to charge the \$180 fee required by 37 C.F.R. § 1.99 and 1.17(p), and any other fees required in connection with this paper, to Deposit Account 16-2500.

The undersigned may be reached by telephone at (212) 969-3246 or by facsimile at (212) 969-2900.

Respectfully submitted,

PROSKAUER ROSE LLP

Dated: July 8, 2005

By: 

Robert S. Mayer  
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1585 Broadway  
New York, NY 10036-8299  
(212) 969-3246

JUL 11 2005

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# Paperless Organ Allocation Program (POAP)

October 2002

# Agenda

- POAP History
- POAP Goals
- POAP Architecture
- POAP User Interface

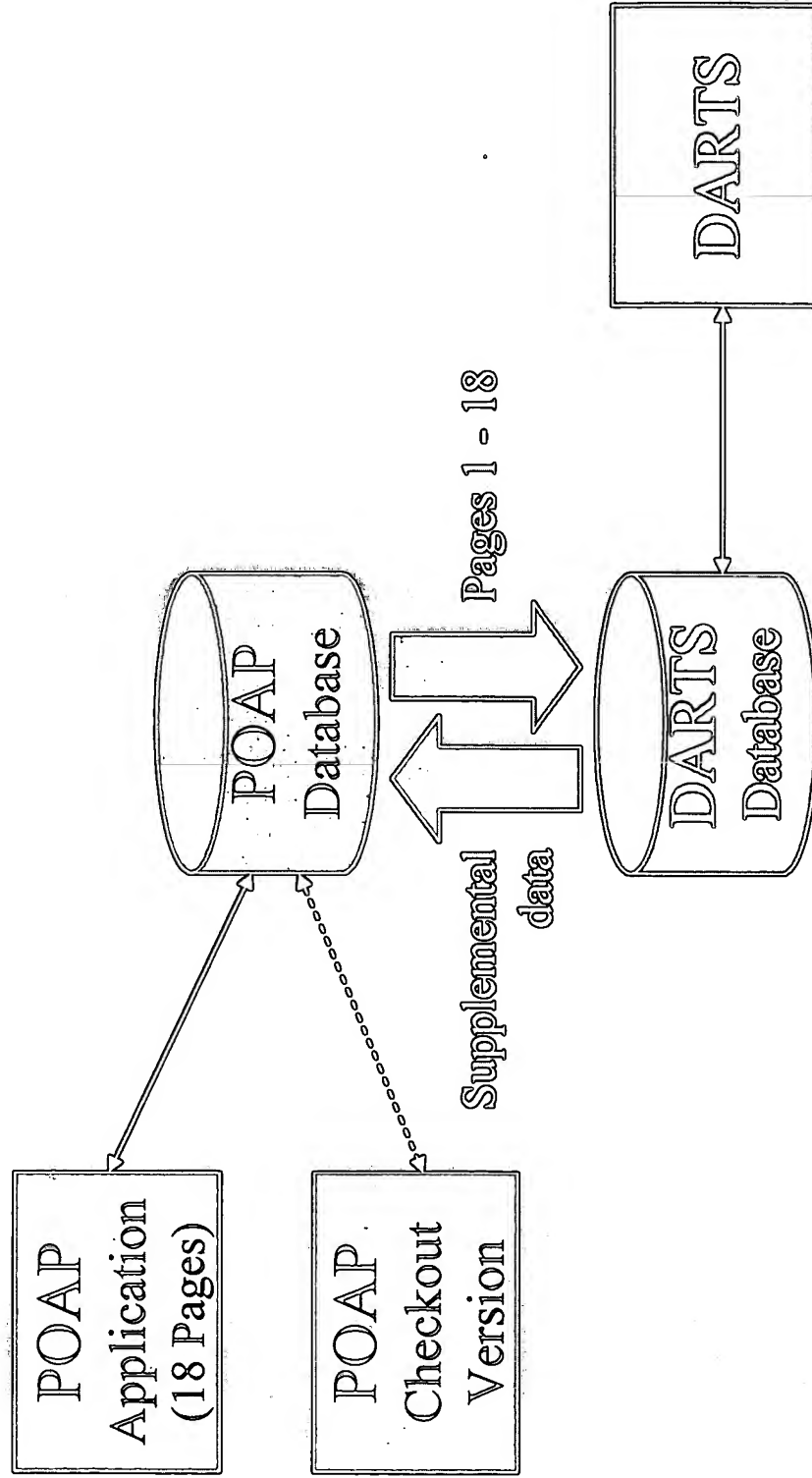
# POAP History

- Joint effort of NYODN & NJOTSN
- Design Effort Began in mid-2001
- Major Input from Staff of Both OPOs
- Beta test to begin late Dec, 2002 or early Jan, 2003

# POAP Goals

- Improve Call Center Function
- Improve Coordinator Productivity
- Provide Clear Data to Transplant Center
- Speed Up Allocation Process
- Allocate More Organs per Donor
- Grow Eventually to Full Database Application

# POAP Architecture





# POAP User Interface

# Security

POAP - Authentication - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites History Links

*Paperless Organ Allocation Program*

Welcome to the Paperless Organ Allocation Program! Please Sign In to Begin.

User Name:

Password:

☐ Remember my user name and password

Done Trusted sites

*Paperless Organ Allocation Program*

## Trusted sites

# Data Entry


POAP - Referral - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Search Favorites History Links

## Paperless Organ Allocation Program

Section - Referral

 **Joe Collier**

Medical Record #

Date/Time of Referral

Locality ☒ Local Provider

Provider

Provider Unit

Telephone #

Fax #

Referring Person

Patient Name

First Last Title

Joe Collier

First Last Middle

Age

Sex

Race

Ethnicity

Height

Feet and Inches

Weight

Pounds

Blood Type

RH Factor

Sub Type

Trusted sites

# Menu

POAP - Referral - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search History Favorites Links

*Paperless Organ Allocation Program*

Section - Referral

Referral Donor Consent Admission Initial Physical Assessment Lab Profile Serologies & Culture Hemodynamics / Temperature Medications / Other Drugs Intake & Output Blood Product / Colloid Cardiac Pulmonary Medical & Behavioral History Intraoperative Renal Liver Heart Lung Pancreas Intestine

68 8/23/2001 17:00 Local Provider P NEW MEXICO DONOR PROGRAM J 3 Fax # Last Title Last Collier Last Middle Years Ethnicity Hispanic: Mexican

5'11 Feet and Inches 150 Pounds A RH Factor + Sub Type 1 Blood Type

Trusted sites

# Graphics

PDAP - Admission - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Search History Favorites

OR

☐ Procedures

☐ Body

☐ Comments

6 - Chest :

Anterior

Posterior

1 - Right Arm  
2 - Left Arm  
3 - Right Leg  
4 - Left Leg  
5 - Abdomen  
6 - Chest  
7 - Head

8 - Right Arm  
9 - Left Arm  
10 - Right Leg  
11 - Left Leg  
12 - Buttocks  
13 - Back  
14 - Head

Save and Close

Done

Trusted sites

<b>POAP - Blood Product / Colloid - Microsoft Internet Explorer</b>			
File Edit View Favorites Tools Help			
Back Forward Stop Home Search History Favorites Links			
<i>Paperless Organ Allocation Program</i>			
Section • Blood Product / Colloid			
Joe Collier			
Blood Product / Colloid Administration Summary			
Date	Time	Type	Volume
6/1/2002	15:35	<input type="text" value="PRBCs"/>	<input type="text" value="20"/> Remove
6/2/2002	17:02	<input type="text" value="FFP"/>	<input type="text" value="10"/> Remove
		<input type="text" value=""/>	<input type="text" value=""/>
Crystalloids Administered 1 Hour Prior to Serology Sample Draw or Cardiac Asystole			
Date	Time	Type	Volume
6/1/2002	17:00	<input type="text" value="Large"/>	<input type="text" value="30"/>
		<input type="text" value=""/>	<input type="text" value=""/>
<input type="button" value="Save and Close"/>			

**POAP - Hemodynamics / Temperature - Microsoft Internet Explorer**

File Edit View Favorites Tools Help

Back Forward Stop Home Search History Favorites Links

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# Paperless Organ Allocation Program

---

Section - Hemodynamics / Temperature

	Remove	Remove
Date	6/1/2002	6/2/2002
Time	15:45	14:00
Average BP	80	79
Heart rate	40	45
High BP	90	93
Duration	10	13
Low BP	50	40
Duration	10	15
CVP		
PA		
PAWP		
CO/CI		
Temperature	97	

Done Trusted sites



# Locally Checked-Out Referrals

POAP Checkout Version - Paperless Organ Allocation Program - Microsoft Internet Explorer

*Paperless Organ Allocation Program Checkout Version*

The following are referrals checked out to your local computer. Select a referral to edit.

Referral / Donor Name	Hospital / Provider	Referral Date & Time
Joe Collier	NEW MEXICO DONOR PROGRAM	Thu 8/23/2001 17:00

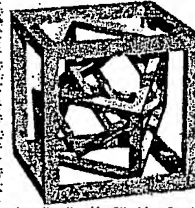
↶ ↷

POAP

Thank You



# R<sup>3</sup> (R-cubed)



Referrals, Reports and Resources

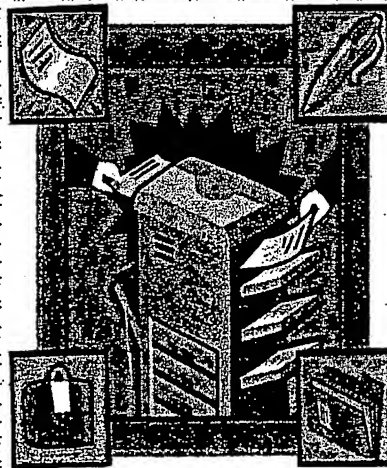
OPO Management Suite

Developed by:

Louisiana Organ Procurement Agency

## Overview

- Call Center.
- Referral, Recipient and Donor medical record management
- UNOS Interface and Placement management
- Donor Registry and DMV Interface
- Management modules include system security, staff, hospital, accounting and development.
- Fully Quality Assured including audit trails.
- Customizable Crystal Reporting system.



## System Software



- Oracle database platform.
- Entirely web-browser based.
- Written in PL/SQL, HTML, Crystal and Java Script allowing for a wide variety of software contractors to work on system.
- No downloads or installations to operate.
- Runs just like a website.

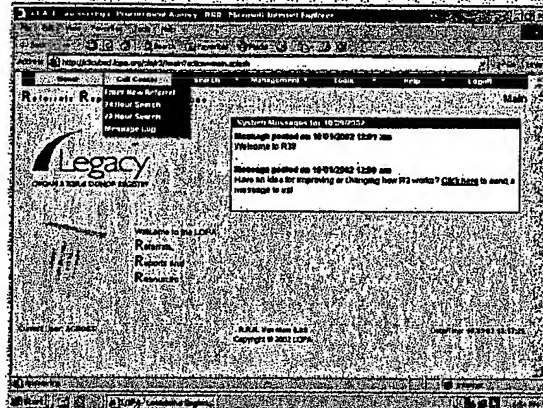
## Design



- System was initially conceived by former Director of Recovery (now ED) and QI / Risk Manager.
- LOPA has expended considerable resources over the past three years in development.
- Design provides for total management of the donation process and OPO.
- R<sup>3</sup> is not simply a DARTS replacement.
- New modules are relatively easy to add - presently adding additional accounting, development, staff scheduling and more.

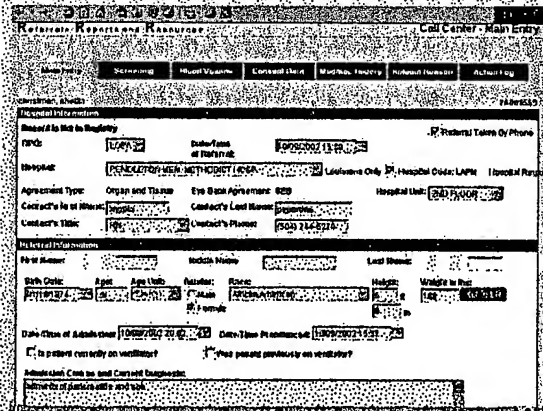
# Call Center

- Provides a system for non-OPD personnel to take referral calls and initiate the donation process including Consent and Medical / Social history.



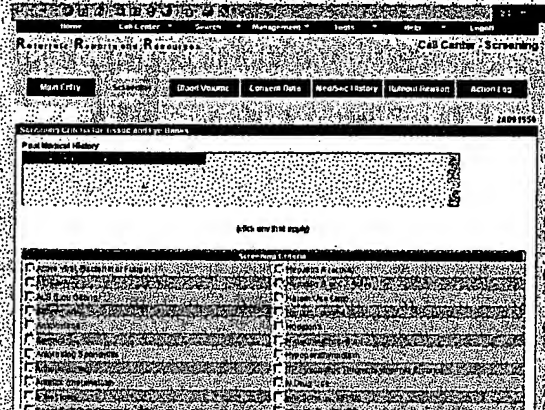
# Call Center

- Designed to function in a streamlined fashion predominantly using keystrokes and tabs.



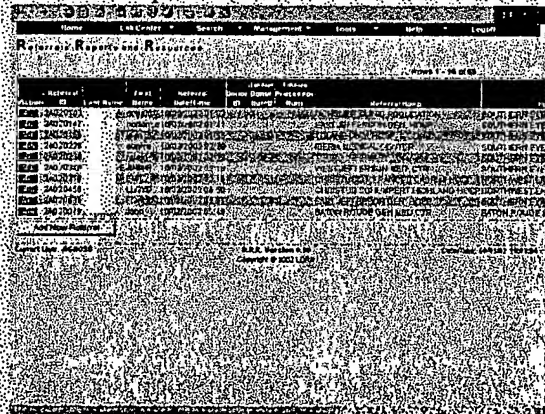
# Call Center

- Automates function of determining tissue and eye ruleouts. Provides for rapid information flow to coordinators on organ eligible referrals.



# Call Center


- Call Center feeds data into the main R<sup>3</sup> database for use with the donation and referral process.






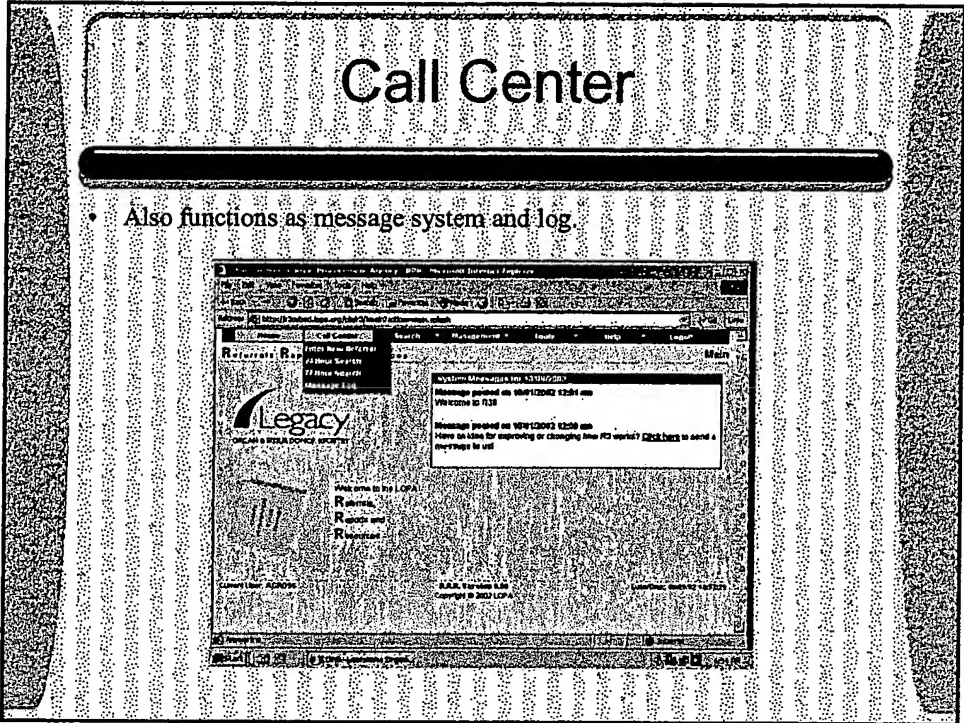
# Call Center

- Also functions as message system and log



The screenshot displays the Legacy Call Center web application. The browser's address bar shows the URL <http://www.legacy.com/legacy/callcenter/>. The page features the Legacy logo and a navigation menu with links for Home, Search, My Messages, and My Profile. A central message box displays a message from 'NEWSPAPER 12345' with the subject 'Message printed on NEWSPAPER 12345 on VINCENZO ID 7138'. Below the message, there is a link to 'Click here to send a message to us'. The footer of the page includes the text 'Copyright © 2001 LCA'.

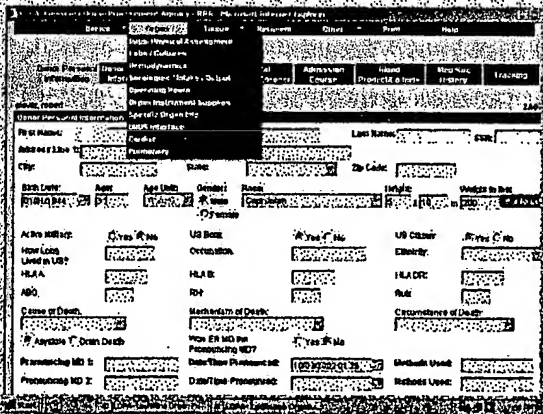
- # Call Center
- Also functions as message system and log
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[illegible]

- [illegible]

# Records Management

- Provides for complete control and management of referral, donor and recipient records



The screenshot displays a software window titled "Records Management" with a menu bar (Service, Records, Patients, Referrals, Reports, Tools, Help) and a toolbar. The main area contains a form for patient information. The "Patient Information" section includes fields for Patient Name, Address, City, State, Zip Code, and Date of Birth. The "Medical History" section includes fields for Active History, US Base, US Clinic, and US Date. The "Donor Information" section includes fields for Donor Name, Address, City, State, Zip Code, and Date of Birth. The "Referral Information" section includes fields for Referral Name, Address, City, State, Zip Code, and Date of Birth. The "Reports" section includes fields for Report Name, Address, City, State, Zip Code, and Date of Birth. The "Tools" section includes fields for Tool Name, Address, City, State, Zip Code, and Date of Birth. The "Help" section includes fields for Help Name, Address, City, State, Zip Code, and Date of Birth.

# Records Management

- Maintains contact and contract information for all hospitals, transplant centers, eyebanks, etc.

The screenshot shows a software window titled "Hospital Information". It contains several sections for data entry:

- Hospital Information:** Fields for Name, Address, City, State, Zip, Phone, Fax, Email, and Website.
- Contract Information:** Fields for Contract Number, Start Date, End Date, and Status.
- Financial Information:** Fields for Payment Method, Payment Frequency, and Payment Amount.
- Notes:** A text area for additional information.

# Records Management

- Provides complete QA trail for record.

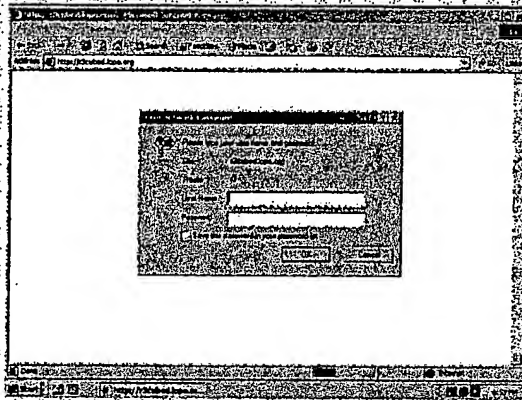
The screenshot shows a software window titled "QA Trail". It contains several sections for data entry:

- General Information:** Fields for Name, Address, City, State, Zip, Phone, Fax, Email, and Website.
- Contract Information:** Fields for Contract Number, Start Date, End Date, and Status.
- Financial Information:** Fields for Payment Method, Payment Frequency, and Payment Amount.
- Notes:** A text area for additional information.



# Records Management

- Records may be updated from any location with Internet access



# Records Management

- Coordinators and technicians can begin and complete paperwork in the field

A screenshot of a web-based form for recording patient information. The form is titled 'Patient Information' and contains various fields for data entry. The fields are organized into sections: 'Patient Information' (Name, Address, City, State, Zip Code), 'Demographics' (Age, Sex, Race, Religion, Marital Status), 'Medical History' (Allergies, Current Medications, Past Medical History, Family History), and 'Vital Signs' (Blood Pressure, Heart Rate, Temperature, Respiration Rate, Oxygen Saturation). The form also includes a 'Save' button and a 'Cancel' button.

# Records Management

- Electronic records can be reviewed on-line by Transplant Center personnel.

The screenshot displays a web-based interface for managing medical records. It features a top navigation bar with tabs like 'Home', 'Search', 'Reports', and 'Tools'. Below this, there's a section for 'Patient Information' with fields for Name, Address, and Contact details. A central area contains a grid of checkboxes and text boxes for clinical data, including 'Active Malignancy', 'Hepatic Encephalopathy', 'Hepatic Failure', 'Hepatic Metastases', 'Hepatic Cysts', 'Hepatic Lipomas', 'Hepatic Hemangiomas', 'Hepatic Adenomas', 'Hepatic Carcinomas', 'Hepatic Sarcomas', 'Hepatic Lymphomas', 'Hepatic Myelomas', 'Hepatic Plasmocytomas', 'Hepatic Ewing's Sarcoma', 'Hepatic Osteosarcoma', 'Hepatic Chondrosarcoma', 'Hepatic Fibrosarcoma', 'Hepatic Leiomyosarcoma', 'Hepatic Rhabdomyosarcoma', 'Hepatic Liposarcoma', 'Hepatic Angiosarcoma', 'Hepatic Hemangioendothelioma', 'Hepatic Kaposi's Sarcoma', 'Hepatic Lymphoma', 'Hepatic Myeloma', 'Hepatic Plasmocytoma', 'Hepatic Ewing's Sarcoma', 'Hepatic Osteosarcoma', 'Hepatic Chondrosarcoma', 'Hepatic Fibrosarcoma', 'Hepatic Leiomyosarcoma', 'Hepatic Rhabdomyosarcoma', 'Hepatic Liposarcoma', 'Hepatic Angiosarcoma', 'Hepatic Hemangioendothelioma', 'Hepatic Kaposi's Sarcoma'. The bottom section includes 'Transplant Information' with fields for 'Transplant Type', 'Transplant Status', and 'Transplant Date'.

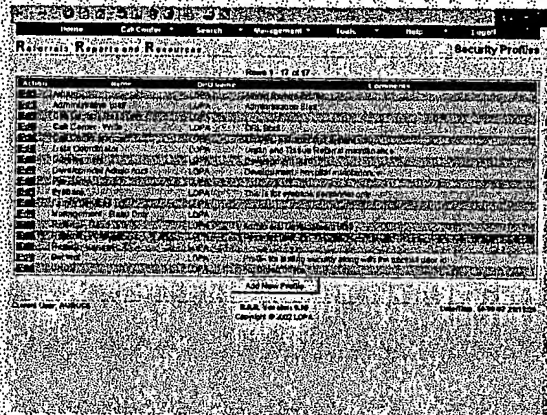
# Security and Management

- Provides a system for 'top-down' management of security and access.

The screenshot shows the 'Legacy' system's security and management interface. It features a top navigation bar with tabs like 'Home', 'Search', 'Reports', and 'Tools'. Below this, there's a section for 'User Management' with a table listing users and their roles. The table has columns for 'User Name', 'User Role', 'User Status', and 'User Last Login'. The bottom section includes 'System Information' with fields for 'System Name', 'System Version', and 'System Date'.

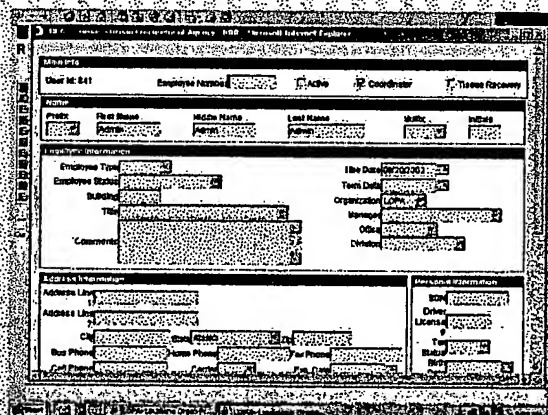
# Security and Management

- Executive Director 'panic button' locks down system.



# Security and Management

- Levels of access are fully controlled and designed by managers.



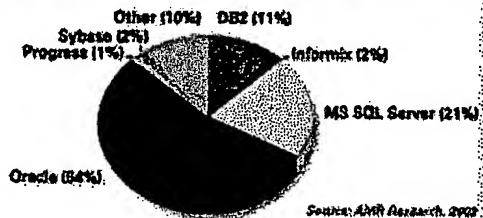
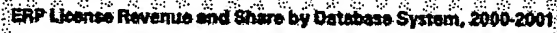
# Security and Management

- All security settings and look up table values are controlled and managed by the Executive Director designate.

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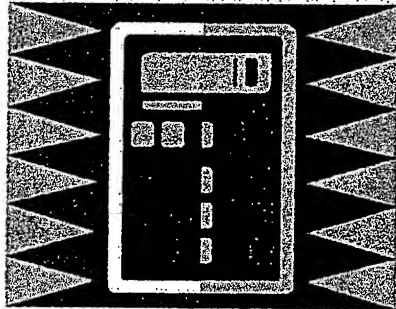
## Security and Management

- Oracle® is famous for rock solid security - no security holes or patches (for which Microsoft® is infamous!)





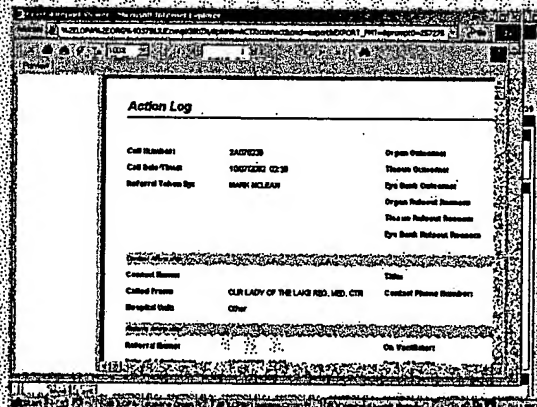
## Other Functions



- System provides invoicing information directly to accounting - increasing cash flow
- Letters to donor families, hospital staff, etc. are automatically generated.
- Automatic system backup both off site and internally within call center.
- Transplant centers can review donor records online at specified and password protected url.
- Double redundant backup operating systems.

## Reporting

- System can provide any number of set reports and provides a system for simple development of customizable reports.

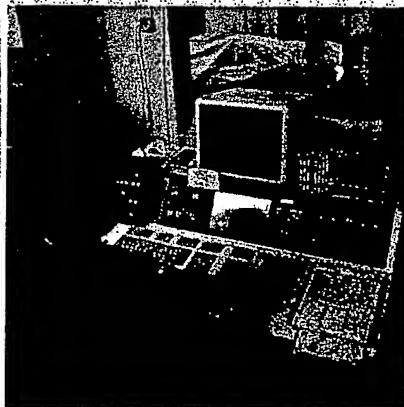


## Reporting



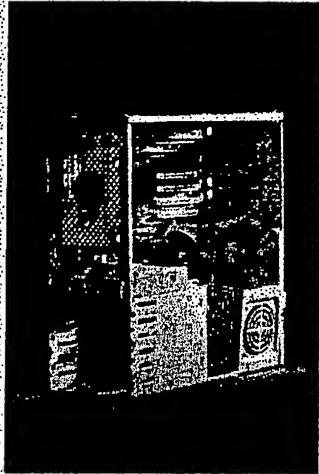
- Full set of basic reports including Donor Report (AOPO form) included with system.
- Options include access to full Crystal Enterprise® system.
- Crystal recognized as the leading report software company in the world.

## Quality Assurance



- System provides a full record of each entry to a file including time, date and user.
- Designed to comply with the requirements of both HIPAA and FDA.
- Ruleout criteria set as determined by various tissue agencies and eyebanks.
- Provides for locking of records once QA accepted.

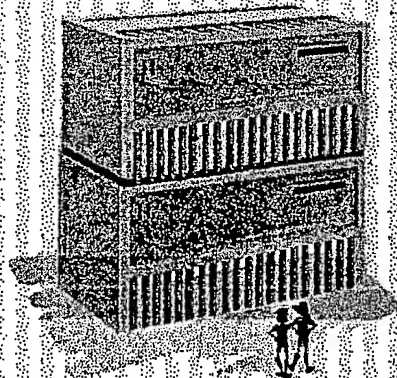
## Advantages



- Scalable system allows for easy addition of modules and growth of users and data.
- Can be customized by the OPO to meet specific needs.
- Development cost can be shared across multiple OPOs.
- Useable as a hosted (shared with separate data base) or stand alone solution.

## Solutions

- Available as a hosted solution which shares the cost of the software design, Oracle® and Crystal® licensing. This still allows for customization of look and feel and look up tables while providing a completely separate database for each OPO.
- Also available as a stand alone customizable application to run on independent server systems.



## For Further Information

- For further information on the R<sup>3</sup> system, please contact:
  - Andrew Gross
  - Ph. 225-937-2462
  - Email: [andrew@healthkiosks.com](mailto:andrew@healthkiosks.com)



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